



America

# CERTIFICATE

No. QS6 078360 0034 Rev. 00

Certificate Holder:



**LAP GmbH Laser Applikationen**  
Zeppelinstr. 23  
21337 Lüneburg  
GERMANY

Certification Mark:



Scope of Certificate:

**Design and Development, Manufacturing, Installation, and Service of Laser Positioning Systems and Patient Verification Systems as well as Products for the Commissioning of Therapy and Diagnostic Equipment in Radiotherapy and Radiation Diagnostics**

Standard(s):

**ISO 13485:2016**

Regulatory Authority(ies):

**Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA Fda. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6\\_078360\\_0034\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:QS6_078360_0034_Rev.00)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

**F007198**

Report No.:

**713313597**

Effective Date:

**2025-01-30**

Expiry Date:

**2028-01-29**

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Date of Issue: 2025-02-05

( Renee Walker )  
Director, US Certification Body, MHS



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**Regulatory Requirements:      Audit/Certification Criteria**

**Australia**

Therapeutic Goods (Medical Devices) Regulations 2002  
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

**Brazil**

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices  
 - RDC ANVISA n. 551/2021  
 - RDC ANVISA n. 67/2009 - Vigilance

**Canada**

- Medical Device Regulations – Part 1- SOR 98/282

**Japan**

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)  
 - Japan PMD Act (as applicable)

**United States**

- 21 CFR Part 803  
 - 21 CFR Part 806  
 - 21 CFR Part 807 – Subparts A to D  
 - 21 CFR Part 820

**Facility(ies):**

**LAP GmbH Laser Applikationen**

Zeppelinstr. 23, 21337 Lüneburg, GERMANY

**Facility Scopes:**

Design and Development, Manufacturing, Sales, Installation, Commissioning and Service of Laser Positioning Systems and Patient Verification Systems as well as Products for the Commissioning of Therapy and Diagnostic Equipment, Quality Control and Assurance in Radiotherapy and Radiation Diagnostics

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